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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,526	06/01/2001	Peter M. Bonutti	BON-1360-7	3309

33771 7590 06/22/2009
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EXAMINER

RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
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3775

MAIL DATE	DELIVERY MODE
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06/22/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/872,526	Applicant(s) BONUTTI, PETER M.	
	Examiner Anu Ramana	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36,38-43,46-50,53,57,59-61,66 and 67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36,38-43,46-50,53,57,59-61,66 and 67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/25/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 25, 2009 has been entered.

Election/Restrictions

Newly submitted claims 68-79 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons.

The invention of independent claim 36 and the invention of independent claim 68 are distinct inventions because: (1) the inventions have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 68-79 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.114, 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 46 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recitation "separated portions of fetal tissue are combined with bone growth promoting substances" is deemed to be new matter. Applicant's disclosure, as originally filed, provides support for removal of bone tissue, fetal tissue etc. but does not provide support for separating fetal tissue, combining the separated fetal tissue with bone growth promoting substances and reimplanting the separated fetal tissue in a patient.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36, 38-40, 46-50, 53, 57, 59-61, 66 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over, Rudall K.M., Wickham, G. A., "Development of wool follicles and fibers on autoplasic grafts of stored foetal lamb skin," pp. 75-88 of book titled "Biology of the skin and hair growth," Americal Elsevier Publishing Company, Inc., 1965 (hereafter Rudall et al.) in view of Kellogg (US 3,606,878).

Rudall et al. disclose the method steps of: making a percutaneous incision in the abdominal wall of a ewe, donor; cutting fetal tissue; irrigating or immersing the tissue in glycerol; maintaining sterility of the excised tissue; treating the graft with a material such as serum or a biodegradable material or polymer or adhesive element or fibrin or "tissue grafts"; and implanting the graft material in a patient, i.e., the delivered lambs (pages 76-78).

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Rudall et al. disclose all elements of the claimed invention except for using a cutting or removal device to excise tissue utilizing suction and irrigation to move tissue along a passage of the device wherein the cutting device includes a flexible shaft, a rigid outer member or cannula, a cutting tip mounted on a distal portion of the flexible shaft, a drive means connected to the flexible shaft, and aspiration openings located on an outer periphery of the cutting tip (pages 1066-1067).

Kellogg teaches a needle instrument for biopsy or tissue extraction including: a rigid outer member or cannula 10; a flexible shaft 22 connected to a cutting tip (24, 26), the cutting tip including aspiration openings 26a, 26b spaced from a distal end of the cutting tip (Figs. 4 and 5, col. 2, lines 40-65, col. 3 and col. 4, lines 1-37).

Regarding claim 38, the step of rotating motion to move the cutter within the cannula is inherent to cutting tissue drawn into the instrument by suction.

Regarding claim 39, Kellogg clearly teaches the use of reciprocating motion, namely, insertion followed by withdrawal, of the cutter within the cannula (col. 3, lines 40-75).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized a cutting device, as taught by Kellogg, to cut tissue in the practice of the Rudall et al. method, since it was well known to use suction in conjunction with cutting to aid extraction of tissue.

The claimed method steps are rendered obvious by the above discussion.

Claims 36, 40-42, 46-49, 50 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kantoff et al. (In Utero Gene Transfer and Expression: A Sheep Transplantation Model - Blood, Vol. 73, No. 4 (March), 1989) in view of Golbus et al. (Fetal tissue sampling - The San Francisco Experience with 190 Pregnancies," West J Med 1989 Apr; 150: 423-430).

Kantoff et al. disclose extracting fetal blood cells or tissue utilizing a catheter, washing or irrigating the extracted tissue with Iscov's Modified Dulbecco's Medium (IMDM), adding polybrene (a polymer) during gene transfer, followed by reinjection of the cells into a fetus or patient.

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Kantoff et al. disclose all elements of the claimed invention except for the use of suction.

Golbus et al. teach extracting a fetal tissue sample in utero under sonographic or endoscopic guidance wherein a needle is used to penetrate or cut tissue, followed by attachment of a syringe to the needle, with application of negative pressure or suction to draw tissue into the syringe (page 423 and 424).

Golbus et al. also teach extracting tissue using suction, immediately followed by, i.e., substantially simultaneously, including the step of irrigating the tissue using saline. It is noted that on page 423, Golbus discloses flushing fetal tissue from the needle by application of saline solution.

Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made to have utilized a syringe, as taught by Golbus et al., for extraction of fetal blood, in the method of Kantoff et al., since it was well known in the art to utilize a syringe with negative pressure or suction to draw a fetal tissue sample.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kantoff et al. and Golbus et al. further in view of Martell (US 4,373,535).

The combination of Kantoff et al. and Golbus et al. disclose all elements of the claimed invention except for an explicit reference to a filter.

It is well known in the art to use a syringe with a filter for blood collection to prevent blood leakage and provide venting (col. 3, lines 12-30).

Thus, it would have been recognized by one of ordinary skill in the art at the time the invention was made that applying the known technique of providing an aspirating syringe with a filter, as taught by Martell, in the method of the combination of Kantoff et al. and Golbus et al. would have yielded predictable results, i.e., blood collection with blood leakage and venting.

Response to Arguments

Applicant's arguments submitted under "REMARKS" in the response filed on February 25, 2009 with respect to the claims have been carefully considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached at (571) 272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR
June 18, 2009

/Anu Ramana/
Primary Examiner, Art Unit 3775